Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,

Petitioners,

—v.—

MERRELL DOW PHARMACEUTICALS, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF THE NEW ENGLAND JOURNAL OF MEDICINE, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, AND ANNALS OF INTERNAL MEDICINE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICI CURIAE*

This brief is submitted on behalf of the New England Journal of Medicine, Journal of the American Medical Association and Annals of Internal Medicine, three of

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* Counsel for the parties have consented to the filing of this brief, and letters of consent have been filed separately with the Clerk.

the world's foremost medical journals, concerning the issue of peer-review. One of the factors that contributes to the high professional standing of these journals is the very rigorous standard of accuracy and reliability they apply to the articles they publish—a standard protected by the peer-review process. Amici submit this brief, in the classic tradition of *amicus curiae* briefs, to familiarize the Court with, and endorse, the uniformly accepted standards of "good science" including publication subject to peer-review. While this brief is submitted in support of respondent concerning the importance of peer-review to good science, Amici take no position on the ultimate issue of whether Bendectin causes birth defects.

DISCUSSION

I. Good Science, The Minimum Standard Of Credibility For Any Research, Requires Peer-Review And Publication

"Good science" is a commonly accepted term used to describe the scientific community's system of quality control which protects the community and those who rely upon it from unsubstantiated scientific analysis. It mandates that each proposition undergo a rigorous trilogy of publication, replication and verification before it is relied upon. Scientific advances occur, in part, because dissemination of results by publication allows scientists to learn about and critique the reported research. In this way, scientists may expand upon what has already been achieved.[1] Peer-review has long been

1 Scientific research is conducted by building upon, and expanding, the research previously performed. As discussed in Section IV, *infra*, if the initial research reported in publications is not a secure block upon which to build, further research will lack a proper foundation.

utilized by technical journals to assure and improve the quality of the information they disseminate and is an essential prerequisite to publication.

Peer-review focuses on the methodology, analysis and results recited in an article in an attempt to weed out error (*e.g.*, from observer bias, improper statistical analysis, insensitive methods, carelessness and failure to recognize and control for confounding variables) and to assure that the text of an article is complete so that readers may judge the work for themselves. In this way, the peer-review process not only reduces the opportunity for reporting errors but assists in improving the quality of the written report and impels scientists to raise the standards of research and writing. *See* Relman and Angell, *How Good is Peer Review?*, 321 New Eng. J. Med. 827, 828 (1989). Its role in the publication process is nonetheless limited. Peer-review does not (and cannot) control what is selected by the editors of a journal for publication; nor can it guarantee that reported results are correct. Its role is to promote the publication of well-conceived articles so that the most important review, the consideration of the reported results by the scientific community, may occur after publication.

Good science requires that a proposition be supported by experimental data, be reduced to writing, and be published after undergoing peer-review *prior to* any reliance thereon. The published article should include enough information about the design, methodology and analysis of the reported experiments or observations to permit other scientists to duplicate and verify the results as a basis for further study. Defense of a proposition before

qualified peers—both in the form of peer-review and post-publication comments such as Letters to the Editor (*see* note 11, *infra*)—is the bedrock of the scientific credibility which justifies, *inter alia*, a court's reliance upon the expression of expert scientific opinion in making findings of fact. Under certain circumstances, an expert's opinion need not undergo peer-review unless the expert seeks to offer a view inconsistent with that previously published in peer-reviewed journals. Where the expert seeks to do so, she must submit the basis of the opinion for peer-review and publication before it is credible.[2] Unlike the biases inherent in litigation—which may skew an expert's opinion or results to benefit one party over another—good science is not primarily concerned with what the results may turn out to be, but rather with the accuracy and reliability of the experimental methodology and data by which they are reached.

In many circumstances, failure to seek peer-review and publication of research or results calls into question not only the ultimate conclusions reached, but also the methodology employed in conducting the research or analyzing the results.[3] This is because unwillingness to

2 Amici do not suggest that all propositions propounded by an expert witness in a lawsuit must be peer-reviewed before they can be relied upon. There are situations, such as the application of an accepted theory to specific facts, in which peer-review might not be necessary or even appropriate. However, propositions propounded by an expert ought to be based upon, or consistent with, data or methodology published in peer-review journals, whenever such are available.

3 In some instances, researchers elect to make the first disclosure of their research or results through other means of publication, such as at conferences or to governmental panels, prior to publication in a journal. This is not necessarily inconsistent with the peer-review process, although it can affect the editorial decisions of some peer-reviewed journals which do not publish previously disseminated research results.

subject one's methodology to review—both during peer-review and by the scientific community after publication—stands as a telling admission that the standards of reliability associated with the peer-review process may not have been met.

Of course, it is unreasonable to expect all scientific analysis to be published in a peer-reviewed journal.[4] However, for certain branches of science, such as biomedical science and, more particularly, epidemiology, bio-statistics and dysmorphology, an expert's conclusions and opinions generally are not relied upon until they have been reduced to writing and published after review by a panel of experts. *See* Relman, *Publishing Biomedical Research: Roles and Responsibilities*, 20 Hastings Center Rep. 23 (May/June 1990). This review—a "cross-examination" of the methodology and analysis by those versed in the technical issues—either establishes the proposition as one which reasonably may be relied upon, or, in the alternative, suggests further work (*e.g.*, revision of the article) thereby protecting the integrity of science.

II. Peer-Review As A Safeguard For The Reliability Of Scientific Propositions Originated in the Mid-18th Century

The origins of peer-review are frequently traced to 1752 when the Royal Society of London, a medical society, began publishing *Philosophical Transactions* and established a "Committee on Papers" to review articles submitted for publication. Kronick, *Peer Review In*

4 For instance, it would be unreasonable to expect that every expert witness testifying at a trial would have submitted and published the opinion at issue, when it may be of no interest outside the context of the case. See note 2, *supra*.

Eighteenth-Century Scientific Journalism, 263 J. A.M.A. 1321 (1990), *citing The Records of the Royal Society of London* (1940 4th ed.) and Ziman, *Information, Communication, Knowledge*, 224 Nature 318 (1969). The Committee, which consisted of at least five members, could call on "any other members of the Society who are knowing and well skilled in that particular branch of Science that shall happen to be the subject matter of any paper which shall be then to come under their deliberations." *Id.* Accordingly, the Committee could solicit pre-publication reviews of a paper from anyone knowledgeable in the field.[5]

It was not until the 19th century, however, that medical journals not affiliated with professional societies came into existence. Burnham, *The Evolution of Editorial Peer Review*, 263 J. A.M.A. 1323, 1324 (1990). The early medical journals were written primarily by their editors or employees (much like newspapers and magazines), and outsiders were not requested to review the articles. Similarly, scientific journals were published as the official record of research institutes and contained articles generated internally, not subject to outside review.

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5 Before the establishment of the Royal Society of London's Committee on Papers, the Royal Society of Edinburgh stated a similar editorial policy in the preface to its 1731 *Medical Essays and Observations*. That policy called for a form of peer-review very similar to that employed today:

> Memoirs sent by correspondence are distributed according to the subject matter to those members who are most versed in these matters. The report of their identity is not known to the author. Nothing is printed in this review which is not stamped with the mark of utility.

Id. (citing 1 *Essais et Observations de médecine de la Société d'Edinbourg* (1740)).

This practice began to change in the late-19th and early-20th centuries when physicians began to specialize in particular fields, a process which spawned a demand for specialized journals. Peer-review by outsiders was nevertheless slow to take hold because many of these journals were personal publications of dominant authors. *Id.*

While many editors were avoiding peer-review in the early 20th century, other prominent editors embraced it, notably those at the *British Medical Journal*. *Id.* at 1325. Still other journals were adopting modified peer-review approaches, such as employing in-house reviewers. For example, when *Surgery, Gynecology and Obstetrics* was founded in 1905, the editor encouraged outside authors to submit articles but wrote that in-house experts would review all articles before publication. Similarly, book publishers recognized the need for peer-review as early as the 19th century and actively sought outside advice on, and review of, book manuscripts in technical fields.[6] *Id.* In the United States, journal editors did not widely adopt peer-review as an integral part of the publication process until after World War II, when a large number of United States medical journals began to adopt the practice. *Id.*

The history of the development of peer-review is not completely documented, and there are many gaps in the record of its evolution prior to World War II. It is clear, however, that the process of peer-review and publication has evolved along with science, and more particularly biomedical science. There can be no doubt that the use

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6 Those publishers, unlike the editors of medical journals, were lay people not expert in the field; so presumably they did not feel qualified to review a technical manuscript. *Id.*

of peer-review by journals to establish the credibility of articles has played a major role in the huge advances that have occurred in scientific and medical research since World War II. (Indeed, it is notable that the briefs of petitioners and many of the Amici supporting them rely heavily on articles published in peer-reviewed journals.) Thus, scientists in all disciplines have recognized the importance of peer-review and publication in developing research which may be relied upon, and so too should this Court.

III. The Peer-Review Process

The publication and peer-review process begins when an article is received by a journal. Articles are usually submitted without solicitation, and a journal's editor pre-screens them to determine if minimum criteria for publication are satisfied. (For example, the editor examines whether the subject matter is relevant to the journal's readership and whether the article is a repetition of prior publications.)[7]

The vast majority of the articles received by a journal which have not been initially rejected by the screening process are then submitted to a panel of outside experts selected on the basis of the paper's content. Typically, a journal maintains its own roster of qualified reviewers, often listing thousands of experts, and selects at least

7 At this stage, by way of example, the New England Journal of Medicine rejects about five to ten percent of the almost 4,000 submissions it receives each year. *The Journal's Peer-Review Process*, 321 New Eng. J. Med. 837, 838 (1989); *see also* Relman, *Peer Review In Scientific Journals—What Good Is It?*, 153 W.J. Med. 520 (1990). The Journal of the American Medical Association, on the other hand, rejects almost 40% of the articles it receives during the preliminary screening.

two for each article. The identities of the reviewers are not required to be disclosed to the author under the peer-review system used by most journals, since it is believed that this frees the reviewers to be as critical and candid as is appropriate without fear of retribution or bias. Relman, *Peer Review In Scientific Journals—What Good Is It?*, 153 W.J. Med. 520 (1990); Relman, *Anonymous Reviews Are Much More Likely To Be Forthright In Their Criticism, Regardless Of The Status Or Reputation Of The Author*, 2 J. of N.I.H. Res. 19 (1990). In addition to the outside reviewers, many journals, such as the Annals of Internal Medicine, also use in-house associate and technical editors who are expert in the relevant fields to review an article.

Once the outside reviewers have completed their assessment, typically within three weeks, they send their two part written reviews to the journal's editorial staff. In the first part, each reviewer provides identifying and background information and an opinion on whether the article should be published, the priority for publication and the article's overall merit.[8] This portion is retained by the editor and not sent to the author. The second part contains the reviewer's itemized substantive comments on the article's content, and a copy of this part is usually provided to the author.[9]

The reviewers' principal function is to identify any analytical problems in an article, as well as inconsistencies, ambiguities or gaps in the stated facts or anal-

8 This part also solicits any information that might indicate the reviewer's bias or any conflict (financial or otherwise) concerning the article or its author.

9 A sample review form used by the Journal of the American Medical Association is reprinted as Appendix A.

yses. In this way, they try to make sure that an author neither overstates nor understates the work or results. However, the reviewers "are consultants, not arbiters of publishability. Peer review is not a straw vote among referees but rather a source of information and technical advice to the editors, who should make the final decision." Relman, *Peer Review In Scientific Journals — What Good Is It?*, 153 W.J. Med. 520, 521 (1990). In advising an editor, the reviewers will indicate whether the article should be published as is, needs revision but should then be published, needs revision and then should be re-reviewed, or should be rejected. Typically, an editor will require an author to revise the article notwithstanding the results of peer-review; and the final decision on whether to publish an article is the editor's, often based upon a number of factors beyond the article itself such as space limitations, timeliness and priority.[10]

As previously discussed, peer-review and publication does not end the scientific inquiry. Indeed, the mere act of publication frequently provokes scientific critique of the article by readers, who often submit Letters to the Editor commenting on the strengths or weaknesses of the work and its implications.[11] Authors almost always

10 Many journals, including Amici, allow an author to dispute any technical or scientific reason for an article's rejection. The author may, for instance, request a new review by other reviewers. However, rejections for non-technical reasons (*e.g.*, repetition of a prior publication) are usually final. Rejected articles typically are resubmitted to other journals by their authors, where they are usually published. *See*, *e.g.*, note 12, *infra*.

11 An important part of every peer-reviewed publication is its forum for questions and/or comments from its readers, usually a Letters to the Editor section. For instance, The International Committee of Medical Journal Editors' "Uniform Requirements for

respond in the same column with additional comments expanding upon or explaining a point in the article. In some instances a letter can lead to corrections or retractions, which then become part of the available scientific literature for further study.

IV. Peer-Review Focuses On The Methodology Reported And The Analysis Of The Results

Peer-review does not entail an audit of the research reported in an article. The author-researcher must be relied upon to accurately and honestly report what occurred or was observed during research, and no review of a manuscript can analyze the accuracy or honesty of the reported observations. "Reviewers cannot, after all, watch the experiments being performed." Relman and Angell, *How Good is Peer Review?*, 321 New Eng. J. Med. 827, 829 (1989). Accordingly, it is not the province of peer-review to certify reported results or prevent fraud; and while it is reasonable to rely upon peer-review as validating the reported methodology or analysis and to confirm that the conclusions are justified by the data, it is unreasonable for the process to do more.

Because peer-review does not, and cannot, inquire into whether the authors actually did what they report, the reviewers cannot assure the readers of the truth of the ultimate conclusion contained in an article. Accord-

Manuscripts Submitted to Biomedical Journals," which have been agreed to by over 400 of the leading journals worldwide, specify that:

> All biomedical journals should have a section carrying comments, questions, or criticisms about articles they have published and where the original authors can respond.

Statements from the International Committee of Medical Journal Editors, 265 J. A.M.A. 2697, 2698 (1991).

ingly, peer-review should neither prevent the publication of articles on the "cutting-edge" of science nor limit the conclusions expressed. It asks only that the conclusions be appropriately based upon good evidence—indeed, it is the hope of a journal editor to publish "cutting edge" articles based upon proper experimental methodology and data, thereby boosting the journal's prestige.[12] Science is the ever-evolving search for elusive truths—with each new discovery everything previously known must be reevaluated. Thus, new scientific breakthroughs in the search for truth, whether Galileo's heliocentrism or the discovery of a treatment for AIDS, are embraced and welcomed by all true scientists; and so too are smaller steps toward the discovery of scientific truths. However, if the new "discovery" has not been reached by good science, including the process of publication and peer-review, then it is not reliable and should not be used by others in the reevaluation of what is known.

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12 In rare instances, reviewers have indicated that an article is not acceptable because it is contrary to "what everybody knows." Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 J. A.M.A. 1438, 1440-41 (1990). Normally, such a suggestion is rejected by the editor. In those rare instances in which an editor declines to publish a paper for this reason, the article is usually published in another journal. Horrobin (*id.*), for instance, cites several examples of articles that were not published in the first journal chosen by the author because of, in part, the results of peer-review (sometimes the rejections are justified but in other cases they may have been the result of inappropriate conduct by competing or jealous peers—similar to Galileo's treatment by those with a non-scientific agenda). However, in all of these cases the articles were eventually published in responsible journals and several resulted in Nobel Prizes based upon the publications (much to the embarrassment of the editors who had rejected the articles). *Id.* At the present time there are over 100,000 scientific and medical periodicals and journals available for such publication world-wide.

A cogent example of the importance of peer-review occurred in March, 1989, when the scientific community was rocked by reports that a method for cold fusion finally had been found. In theory, cold fusion allows nuclear energy to be harnessed without creating radioactive waste by combining atoms instead of destroying them; but for years scientists had tried to reduce the theory to practice without success. Because of the importance of their "discovery," the two researchers who announced it decided to by-pass the usual peer-review and publication process and go public with their results. Millions of dollars and research hours were then invested by others to support continued research. Although the two researchers initially refused to disclose the details of their original experiments, it has now been determined that what the researchers thought was cold fusion was really a series of errors compounded by their failure to follow the good science of peer-review and publication. *See* Broad, *Cold-Fusion Claim is Faulted On Ethics As Well As Science*, N.Y. Times, March 17, 1991, at 1, col. 1; *see also* Hall, *Perpetual Motion It Isn't* (Book Review), L.A. Times, May 12, 1991 at 11 (reviewing Close, *Too Hot to Handle: The Race For Cold Fusion*). Amici submit that if the researchers had submitted their results for peer-review and publication, as mandated by good science, their error would have been recognized before millions of dollars and much time and effort were wastefully expended based upon invalid methodology and analysis resulting in incorrect conclusions. *See* Broad, *Cold Fusion Still Escapes Usual Checks of Science*, N.Y. Times, October 30, 1990, at 1, col. 1.

On the other hand, recently many advances have been made in superconductivity, which allows the transmis-

sion of energy over long distances with virtually no loss due to resistance. Those researchers diligently followed the precepts of peer-review and publication and achieved a major breakthrough. *See* Van, *Superconductivity Nears Practical Use*, Chicago Trib., February 10, 1992, at Business 1; *see also* Browne, *Chemists' New Toy Emerges As Superconductivity*, N.Y. Times, September 3, 1991, at C-1, col.1.

The virtues of peer-review in ensuring proper methodology and analysis of research are obvious. Proper prepublication peer-review is the only safeguard that exists to establish reliability of articles and prevent publication of incorrect conclusions.

V. Peer-Review's Role In Determining The Admissibility Of Scientific Propositions

The question before the Court is not the role of peer-review and publication in scientific research—science itself has already determined its paramount importance. The Court must determine the role of publication in peer-reviewed journals as part of good science under the rules of evidence.

At issue is whether, under the Federal Rules of Evidence, a court may exclude from evidence, or find insufficient, an expert's opinion if it contradicts an existing body of scientific work published in peer-reviewed journals and others in the field would not recognize it as having been validly reached, *e.g.*, by good science employing the checks of publication subject to peer-review. As recognized by the Ninth Circuit (951 F.2d 1128, 1131), as well as the First, Fifth and D.C. Circuits,[13] a court should look to whether the proposition

13 *See Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (*en banc*), *cert. denied*, 112 S. Ct. 1280 (1992);

being set out by an expert is in accordance with published scientific data whenever available—data developed by good science, utilizing publication and peer-review standards which exist independent of the biases inherent in litigation—before finding the opinion admissible or sufficient to establish a *prima facie* case. It is elementary that this inquiry should not be governed simply by the ultimate conclusion reached by the expert, but by the methodology and analyses used in reaching it in the context of any already published results.

Equally important to good science, and therefore the rules of evidence, is that the converse is not true: Results which have survived the peer-review process are not immune from further review or attack. Peer-review does not guarantee that results are error free. Publishing research results in a peer-reviewed journal does not end the research inquiry; it merely advances the knowledge with which research is conducted. The reported results become a building block upon which further research is based; and subsequent research, such as a replication of or attack on the initial results, forms the basis of continuing study once published in a peer-reviewed journal.

Subsequent work may seek to disprove the prior analysis or inquire into the researcher's methods or results. However, the new research must also be conducted under the rigors of good science before it may be relied upon. Moreover, research to prove a new proposition or refute earlier work—and thereby invalidate both the work and anything that builds upon it—must also be peer-reviewed, although it must be scrutinized more rigor-

Kropinski v. World Plan Executive Council—U.S., 853 F.2d 948, 956 (D.C. Cir. 1988); *Lynch v. Merrell-National Laboratories*, 830 F.2d 1190, 1194-95 (1st Cir. 1987).

ously than confirmatory research because of the inherent difficulties that would result if incorrect conclusions were relied upon.

The goal of publication and peer-review, as part of good science, is to prevent premature reliance on certain propositions by the scientific community before the supporting evidence has been reviewed by a panel of expert peers and published for all to see; the goal of the rules of evidence, as part of due process, is to prevent premature reliance on certain propositions by a fact finder before it has been found probative, relevant and reliable. Neither guarantees the accuracy of the information or assesses its weight in finding the truth. But both establish a threshold level of reliability. In either situation it would be imprudent to rely upon a proposition before, at a minimum, it has been passed upon for plausibility.

The only mechanism available to assess the credibility of a scientific opinion crucial to the question of liability, independent of the biases of litigation, is to confirm that the opinion was reached by good science, *e.g.*, based upon published evidence that has been peer-reviewed, and then subject to replication and verification. Accordingly, were this Court to repudiate peer-review—an action which Amici strongly oppose—there would be no objective standard for a court to apply in evaluating the credibility of a scientific opinion. Peer-review and publication of scientific data and conclusions, simply put, are the only available non-biased checks on scientific opinion available to the courts and should, therefore, be employed to the extent feasible.

January 19, 1993

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MEDICAL ASSOCIATION, and
ANNALS OF INTERNAL MEDICINE
as *AMICI CURIAE*.

APPENDIX

[LETTERHEAD OF THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION]

RE: MS #

Dear

We would be grateful if you would review the enclosed manuscript and comment on its suitability for publication.

Please use the enclosed forms for your opinion. Provide your comments and suggestions to the editorial office on page 1 and those to the author on pages 2 and 3. You should *not* comment on the acceptability of the manuscript on pages 2 and 3. If your comments are prepared on a word processor, you may print them out on your own paper. Please provide four copies, if possible.

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We recognize that most conflicts of interest are not disqualifying, but request that you indicate any conflict in the space provided on the form. If you perceive that you have a disqualifying conflict of interest, either financial or otherwise, please return the manuscript unreviewed (if possible, with the names of alternative reviewers). This will not affect your reviewer status in any way.

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Please return your review by . If this is not possible, please return the enclosed manuscript packet without delay.

Many thanks for your help.

Sincerely yours,

Deputy Editor, *JAMA*

Enclosure

Page 1

The Journal of the American Medical Association

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COMMENTS FOR EDITORIAL OFFICE

Manuscript Number ____ Manuscript Classification _____

Manuscript Title _____

Author(s) _____

JAMA Editor _____

Date Sent to Reviewer ____ PLEASE RETURN BY _____

RECOMMENDATION

- ❑ Accept as is
- ❑ Accept if suitably revised
- ❑ Revise and reconsider
- ❑ Reject

QUALITY

- ❑ Superior
- ❑ Good
- ❑ Fair
- ❑ Poor

PUBLICATION TIMING

- ❑ Routine
- ❑ ASAP
- ❑ Fast track

PRIORITY

(Low) 1 2 3 4 5 (High)

REFER TO ANOTHER AMA JOURNAL?

- ❑ *Am J Dis Child*
- ❑ *Arch Dermatol*
- ❑ *Arch Fam Med*
- ❑ *Arch Gen Psychiatry*
- ❑ *Arch Intern Med*
- ❑ *Arch Neurol*
- ❑ *Arch Ophthalmol*
- ❑ *Arch Otolaryngol Head & Neck Surg*
- ❑ *Arch Pathol Lab Med*
- ❑ *Arch Surg*

VALUE	YES	NO	UNCERTAIN	N/A
Material original?	❑	❑	❑	❑
Data valid?	❑	❑	❑	❑
Conclusions reasonable?	❑	❑	❑	❑
Information important?	❑	❑	❑	❑
Writing clear?	❑	❑	❑	❑
General medical interest?	❑	❑	❑	❑
Tables/figures appropriate? If not, explain.	❑	❑	❑	❑
Editorial needed?	❑	❑	❑	❑
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